REMARKS

Claims 1-17 remain in the application. Claims 1, 3, 6, 7, 10, 11, 12, 13, 14, 15, 16, and 17 are in independent form. The presently pending independent claims have been amended to place the present application in condition for allowance or at least in better condition for appeal. These claims have been amended in accordance with suggestions set forth in the outstanding Office Action, suggestions discussed during a personal interview with the Examiner, and to further clarify the present invention.

Applicants are grateful for courtesies extended by the Examiner during a personal interview conducted with Applicants' representatives, Kenneth I. Kohn and Andrew M. Parial, November 13, 2002. During the interview, the scope of the claims and the rejections set forth in the Office Action were discussed. Specifically, the Examiner had presented suggestions regarding the scope of the claims, wherein the claims could be limited to a conjugated protein as opposed to a fused protein. Further, the present invention can differ from the prior art if a synergistic relationship between the two peptides exists, wherein one peptide of the conjugated protein enhances the effect of another peptide in the fused or conjugated protein.

Pursuant to the interview, Applicants have amended the claims, without prejudice, in order to clarify further the present invention. Specifically, the claims of the present invention describe the protein of the present invention as a "recombinantly conjugated" protein as opposed to a "fusion" protein. Support for this type of protein can be found on Line 31, Page 7 to Line 27, Page 8 of the specification. This amendment has been made without prejudice in order to expedite the allowance of the present application.

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,684,145 to Van der Zee, et al. and the Mittal, et al. reference. In response thereto, Applicants submit that the presently pending claims are not obvious in view of the cited prior art references.

The Van der Zee, et al. patent discloses a vaccine including a GnRH peptide conjugated to *E. coli* fimbrial-filaments, wherein the vaccine elicits an immune response against GnRH. The Mittal, et al. reference discloses a recombinant form of gD from BHV-1 inserted into a human adenovirus type 5 vector.

The rejection involves a single issue with regard to establishing a *prima facie* case of obviousness. Specifically, a fact-based explanation is needed as to why one of ordinary skill in the art at the time the invention was made would have been motivated to substitute the strong immunogenicity of BHV-1 gD taught by Mittal, et al. with the *E. coli* fimbrial subunit portion of the hybrid protein disclosed in the Van der Zee, et al. patent to evoke an immune response against GnRH and protect against BHV-1 infection.

The cited prior art, however, does not disclose the claimed invention. Specifically, the prior art does not disclose nor suggest a recombinantly conjugated protein including a first proteinaceous portion analogous to all or part of a peptide of known structure and function endogenously synthesized within the vertebrate, the activity of which peptide is to be inhibited within the vertebrate, and which proteinaceous portion by itself is incapable of eliciting an effective immunoinhibitory response in the vertebrate and a second proteinaceous portion analogous to all or part of an immunogen from a pathogen, which the pathogen is capable of pathogenically infecting the vertebrate, recombinantly conjugated to the first proteinaceous portion. Moreover, the prior art does not disclose nor suggest that the second proteinaceous portion causes the vertebrate's immune system to recognize the first proteinaceous portion and produces a response that inhibits the activity of the peptide of known structure and function endogenously synthesized within the vertebrate, protects the vertebrate from known infection caused by the pathogen, and synergistically affects the first proteinaceous portion by enhancing inhibition of the activity of the peptide that is analogous to the first proteinaceous portion.

An advantage of the present invention is the ease of administering an injection to an animal. Animals placed in feedlots are vaccinated numerous times or administered various medications and/or treatments. For example, an animal can be injected with a vaccine for preventing BHV-1 infection and another injection could be for the improvement of animal growth rate or improvement of meat quality (i.e, injection of GnRH). Obviously, there are numerous problems associated with multiple injections ranging from discomfort to the animal, increased costs, decreased efficiency, etc. More importantly, however, the effectiveness of one injection can be decreased as a result of separate injections. If an injection is given to an animal for GnRH, then increased growth of the animal can be affected by a disease or other illness. As a result, by administering with the injection of an immunogen directed against the disease or illness, the resulting effect of the injection of GnRH will be enhanced. In other words, there is a synergistic relationship that exists.

The presently claimed invention provides for the synergistic relationship between the second proteinaceous portion that is immunogenic and the first proteinaceous portion that is analogous to a part or all of an endogenously synthesized peptide of known structure and function. This synergistic relationship is neither disclosed in either prior art references nor is it suggested. As a result, the present invention is nonobvious in view of the cited prior art references.

Based on facts well known to those of skill in the art, the present invention as claimed is patentably distinct over the prior art references because one of ordinary skill in the art would not know to produce, or have a reasonable expectation of success in producing, the claimed invention since there is no reason to believe that the combined protein would have active immunogenic sites once the strongly immunogenic BHV-1 gD is combined with the antigenic determinant of GnRH of the protein disclosed in the Van der Zee, et al. patent.

The components of the claimed invention are merely mentioned in the cited prior art references and there is no suggestion in the prior art to combine the teachings disclosed in the prior art references so that the desired function

of the presently claimed invention could be achieved. There is no suggestion in the prior art references, nor would one be motivated to combine these references, as set forth in the outstanding office action. There is no factual basis set forth in the outstanding office action for a reasonable expectation of success to do so. One would have to ignore the critical teachings of the prior art references in order to combine select features of the references to derive the presently claimed invention. Such picking and choosing can be only done through improper hindsight.

As a result of these claimed differences over the prior art and lack of suggestion and motivation to modify the references or to combine the references, the present invention is patentably distinct. Reconsideration of the obviousness rejection is respectfully requested.

The remaining dependent claims not discussed above are ultimately dependent upon at least one of the independent claims discussed above. No prior art reference makes up for the deficiencies of that reference as applied against the independent claims, as no prior art reference discloses or suggests the invention as set forth in the claims as discussed in detail above.

It is respectfully submitted that the present Amendment places the application in condition for allowance as it removes all remaining issues in dispute. Specifically, the Amendment follows suggestions set forth in the Office Action and clarifies the present invention. As a result, no remaining issues are in dispute. Since there is no prior art cited against any of these claims, it is respectfully submitted that all of the claims are in condition for allowance. It is also respectfully submitted that the present Amendment places the application in condition for appeal. The claims have not been made broader in scope, thereby requiring no further searching, nor do the claims raise any new issues. In fact, all claims now include limitations of previously pending claims and were therefore previously searched.

It is respectfully requested that the present Amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. The

claims have also been amended to clearly distinguish them over the prior art. The application is made at least in better condition for appeal as the Amendment removes any issues, thereby simplifying the issues on appeal. That is, each and every rejection has been overcome. Hence, it is respectfully requested that the Amendment be entered.

Applicants respectfully request to be contacted by telephone if any remaining issues exist.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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CERTIFICATE OF MAILING/TRANSMISSION

I hereby certify that this correspondence is being transmitted by facsimile to the Patent and Trademark Office at (703) 308-4242 on November ___, 2002.

Marie M. DeWitt

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Twice Amended) A [fusion] recombinantly conjugated protein for producing a dual immune response in a vertebrate, which fusion protein comprises:

[(a)] a first proteinaceous portion analogous to all or part of a peptide of known structure and function endogenously synthesized within the vertebrate, the activity of which peptide is to be inhibited within the vertebrate, and which proteinaceous portion by itself is incapable of eliciting an effective immunoinhibitory response in said vertebrate; [connected to] and

[(b)] a second proteinaceous portion analogous to all or part of an immunogen from a pathogen, which the pathogen is capable of pathogenically infecting the vertebrate, recombinantly conjugated to said first proteinaceous portion, [;] wherein said [the] second proteinaceous portion [(b)] caus[ing]es the vertebrate's immune system to recognize [the] said first proteinaceous portion [(a)] and produces a response that:

(i) inhibits the activity of [the] said peptide of known structure and function endogenously synthesized within the vertebrate; [and]

(ii) protects the vertebrate from known infection caused by the pathogen, when the vertebrate is vaccinated with an effective amount of the [fusion] recombinantly conjugated protein[.]; and

(iii) synergistically affects said first proteinaceous portion by enhancing inhibition of the activity of the peptide that is analogous to said first proteinaceous portion.

3. (Twice Amended) A [fusion] recombinantly conjugated protein for producing an immune response in a vertebrate, which [fusion] recombinantly conjugated protein comprises:

[(a)] a first proteinaceous portion analogous to all or part of a peptide of known structure and function, the activity of which is to be inhibited within the vertebrate, and which said first proteinaceous portion by itself is incapable of eliciting an effective immunoinhibitory response in the vertebrate; [connected to] and

[(b)] a second proteinaceous portion analogous to all or part of a BHV-1 antigen recombinantly conjugated to said first proteinaceous portion, [;] wherein, said [the] second proteinaceous portion [(b)] caus[ing]es the vertebrate's immune system to recognize [the] said first proteinaceous portion [(a) and], produces an immune response capable of inhibiting the activity of said peptide within the vertebrate when the vertebrate is vaccinated with an effective amount of the fusion protein, and synergistically affects said first proteinaceous portion by enhancing inhibition of the activity of the peptide that is analogous to said first proteinaceous portion.

11. (Twice Amended) A dual-function vaccine which comprises a [fusion] recombinantly conjugated protein according to claim 1, a vector according to claim 7, or a transformed cell according to claim 10, in an amount effective to [I)] inhibit the activity of the peptide of known structure and function from which a first proteinaceous portion [(a)] of the [fusion] recombinantly conjugated protein is derived[,]; [and II)] to protect against known infection caused by the pathogen from which a second proteinaceous portion [(b)] of the [fusion] recombinantly conjugated protein is derived; and a carrier acceptable for pharmaceutical or veterinary use.